

REMARKS

Applicant acknowledges with appreciation the Examiner's withdrawal of the objection relating to informalities in Claims 39 and 44 in Office Action Paper No. 122804 mailed January 11, 2005. Applicant acknowledges with appreciation the Examiner's withdrawal of the rejection of Claim 53 under 35 U.S.C. § 112, first paragraph, also as set forth in the Office Action Paper No. 122804.

Rejection of Claims 35- 54 Under 35 U.S.C. § 103(a)

Claims 35-54 stand rejected under 35 U.S.C. § 103(a) in view of Knudsen et al., U.S. 6,458,924 (hereafter the '924 patent). Applicant submits that the cited applications do not establish a prima facie case of obviousness because the cited applications do not teach or suggest all the elements of the Applicant's claims. Further, it also appears to the Applicant that the '924 patent cannot properly claim priority under 35 U.S.C. § 119(e) to cited application US 60/035,904 (hereafter the '904 application) because there are no common inventors between the '924 patent and the '904 application. As Applicant submits that the subject matter of the '924 patent relied upon in rejecting the present claims is not present in the cited applications, Applicant herewith submits an affidavit establishing a reduction to practice of the claimed invention before the potential effective filing date of the subject matter of the '924 patent relied upon in rejecting the present claims.

A. Provisional Applications US 60/035,904 and US 60/036,255 do not support a prima facie case of obviousness.

Applicant submits that the disclosure provided by US 60/035,904 (hereafter the '904 application) and US 60/036,255 (hereafter the '255 application) do not establish a prima facie case of obviousness.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claims limitations. MPEP 706.02(j).

1. The '904 and the '255 applications do not teach or suggest all the claimed limitations of the pending claims.

It appears to the Applicant that the subject matter relied upon in rejecting the Applicant's claims is not present in the cited applications. Specifically, a review of the '904 and the '255 application demonstrates there is no mention of a "tween polymeric surfactant" nor is there any mention of a pH range of 3-8 in the cited applications. Further, a review of US 60/036,226 (hereafter the '226 application), filed on January 25, 1997, a day after the cited applications and to which the '924 patent claims priority, reveals that there is also no mention of a "tween polymeric surfactant" nor of a pH range of 3-8 in the '226 application. As the Applicant's claims recite a "tween polymeric surfactant" and it appears that the disclosures do not teach or suggest a "tween polymeric surfactant" or a pH range of 6.5-9.0, a prima facie case of obviousness has not been established.

2. The '904 and the '255 applications do not provide any motivation or suggestion to modify their disclosure to arrive at the claimed invention.

It appears to the Applicant that following the teachings in the '904 or the '255 applications with regard to formulations, leads to formulation instability. As described in Example 4 of the present Application, a GLP-1 formulation containing a buffer, a preservative, and an isotonicity agent, as taught in the '904 and the '255 applications resulted in a hazy formulation when incubated at 4°C and returned to room temperature. However as Example 4 further demonstrates, formulations containing a GLP-1 analogue, a buffer, a preservative, and an isotonicity agent (glycerin) with tween surfactants at a pH of 8.0 returned to clear solutions upon the returning of the formulation to room temperature after incubation at 4°C. Applicant specifically discloses that the addition of a tween surfactant increased the stability of the formulation. (P.16 lines 5-6). Since the '904 and the '255 applications did not recognize that the teachings they provided would result in formulation instability in the absence of tween surfactants, there is no motivation in the provisional applications to modify their disclosure to arrive at Applicant's claimed invention.

B. The '924 patent cannot properly claim priority to the '904 application.

It appears to the Applicant that the reliance on the '904 application as a priority document for the '924 patent is improper under 35 U.S.C § 119(e) because there are no common inventors between the '904 application and the '924 patent. The '904 application appears to be assigned to the Procter & Gamble Company with named inventors Alan D. Wiley, Anthony Harriman, Brian Jeffreys and David W. Ingram. The '924 patent names as

inventors Olaf Huusfeldt, Franklin Nielsen, and Liselotte B. Knudsen. As there are no common inventors between the patent and the provisional application as required by 35 U.S.C. § 119(e), the claim to priority is improper.

Applicant further submits that an error in the claiming of priority by the '924 patent may have occurred as a review of US 60/035,905 (hereafter the '905 application), the next serial number, filed on the same day as the '904 application, reveals that the '905 application is assigned to Novo Nordisk, the same assignee as the '924 patent and has common inventors with the '924 patent. In addition, information from the US Patent and Trademark Office PAIRS system indicates that the '810 application to which the '924 patent claims priority also claims priority to the '905 application, suggesting the '905 application is the correct priority document.

Assuming arguendo the '905 application is the proper provisional application to which priority was sought, the disclosure provided by the '905 application alone or in combination with the '255 or '226 application also does not establish a prima facie case of obviousness because it appears to the Applicant that the '905 application also does not disclose "tween polymeric surfactants". Further, the '905 application does not disclose the pH range of 3.0-8.0 as relied upon by the Examiner in rejecting the Applicant's claims.

Applicant respectfully submits that a prima facie case of obviousness has not been made and request that the rejection under 35 U.S.C. § 103(a) be withdrawn because there is not motivation provided in the '905, the '255, and the '226 applications to modify their disclosure to arrive at Applicant's invention, there is no expectation of success, and all the limitations of Applicant's pending claims are not disclosed, explicitly or inherently, by the '905, the '255, and the '226 applications.

C. **Applicant has antedated the potential effective filing date of the subject matter relied upon in rejecting the present claims.**

Applicant has demonstrated that the subject matter of the '924 patent used in rejecting the present claims is not present in the cited applications and is not in the '226 application. The next application to which the '924 patent claims benefit is US 08/918,810 filed on August 26, 1997 (hereafter the '810 application). However, Applicant herewith submits a declaration under 37 C.F.R. 1.131 by the Inventor/Applicant James Arthur Hoffmann wherein he demonstrates an actual reduction to practice of the presently claimed invention before the filing date of the '810 application. Applicant also herewith submits a copy of Mr. Hoffmann's notebook (Exhibit A) detailing the reduction to practice of the claimed invention.

Rejection of Claims 35-53 and 54 Under the judicially created doctrine of obviousness-type double patenting

Claims 35-54 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,358,924 in view of the Knudsen et al, '924 patent. Upon a notice of allowance, Applicant will file a terminal disclaimer over US 6,358,924, which Applicant submits, will traverse Examiner's rejection.

Conclusion

Applicant believes that the rejections submitted by the Examiner have been traversed and respectfully ask that the Examiner allow all pending claims.

Respectfully submitted,



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